

REMARKS

Reconsideration of the present application in light of the above amendments and the following remarks is respectfully requested. Claims 2-4 have been canceled by way of this amendment, the subject matter of which has been incorporated into claim 1. By way of this amendment, claims 1, 5, 7, 10-16, 25 and 26 are pending. Claim 1 has been amended for clarification. Support for the amendment can be found throughout the specification and claims as originally filed, for example, at line 25, page 8-line 20, page 9; lines 1-26, page 18 of the instant specification.

Priority Claim

Applicant thanks the Examiner for granting benefit as a CIP of prior-filed application US 08/484,593 (now U.S. Patent No. 6,387,650) under 35 U.S.C. § 120 for claims 1-6 and 10-16. Applicant thanks the Examiner for granting benefit to provisional application number 60/228,956 under 35 U.S.C. § 119(e) for claim 7.

Claim Objection

Claim 4 stands objected to as the *E.coli* strain identifier OH157 was italicized. Applicant thanks the Examiner for pointing out this typographical error. Applicant submits that claim 4 has been canceled, thus rendering this claim objection moot. Applicant further submits that the content of claim 4 was incorporated into currently amended claim 1, where the OH157 strain identifier has not been italicized. Accordingly, Applicant respectfully requests this objection be withdrawn.

Claim Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1-6 and 10-16 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to describe the invention in such a way as to reasonably convince one of skill in the art that Applicant was in possession of the claimed invention at the time the application was filed. Specifically, the Action alleges the claims do not recite the conditions under which the conditionally detectable marker can be detected.

Applicant respectfully traverses this rejection and submit the specification fully supports the present claims. Applicant submits claim 1 has been amended for clarification purposes, in order to recite that the conditionally detectable marker undergoes a color change when reacted upon by a viable microorganism in the sample. Support for this amendment may be found in the specification, for example at line 27, page 8—line 1, page 9, where “conditionally detectable” refers to the condition of viability. Thus, Applicant submits the claims are clearly supported by the instant specification, including the conditions under which the conditionally detectable marker may be detected.

Accordingly, Applicant submits this rejection has been obviated and respectfully request the rejection be withdrawn.

Claim Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1-7 and 10-16 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention at the time the application was filed. In particular, the Action alleges the claims do not recite the conditions under which the conditionally detectable marker can be detected.

Applicant respectfully traverses this rejection and submit claim 1 has been amended for clarification and in order to recite conditions under which the conditionally detectable marker can be detected. Support for this amendment may be found throughout the specification and in particular, at line 27, page 8—line 1, page 9. Accordingly, Applicant respectfully submits this rejection has been overcome and request it be withdrawn.

Claim Rejection under 35 U.S.C. § 102(b), First Rejection

Claims 1-6 and 10-16 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Carr et al (U.S. Patent No. 5,064,756). Specifically, the Action alleges Carr et al teaches a kit for antibiotic testing comprising a growth medium, antibiotics and one or more fluorogens along with an aminopeptidase substrate 7-N-(alanyl)-7-amido-4-methylcoumarin.

Applicant respectfully traverses this rejection and submit the cited reference does not contain each and every element of the claimed invention. In particular, Applicant submits the reference does not disclose a composition for detecting a target microorganism in a sample, comprising a conditionally detectable marker that undergoes a color change when reacted upon by a viable microorganism in the sample, and a substrate for an aminopeptidase, wherein said aminopeptidase is substantially absent from the target microorganism, wherein said target microorganism is selected from the group consisting of *Salmonella*, *Listeria*, *E.coli* OH157, *Campylobacter*, *Staphylococcus aureus*, *Cryptosporidium*, and *Giardia*, wherein said substrate comprises a signal moiety, the signal moiety capable of providing a detectable signal when cleaved by substantially all non-target microorganisms, and wherein said conditionally detectable marker and said substrate for an aminopeptidase are not the same molecule.

Applicant submits the cited reference merely discloses methods and compositions for determining the susceptibility of microorganisms to antibiotics, wherein a positive result from the aminopeptidase substrate indicates a particular microorganism is susceptible to the antibiotic substance, for example, as determining a minimum inhibitory concentration (MIC) of an antimicrobial substance. Applicant submits the presently claimed invention comprises—among other things—a substrate for an aminopeptidase that is substantially *absent* from the target microorganism. Applicant submits this element—and others—is not taught by the cited reference.

Accordingly, Applicant submits the cited reference does not anticipate the presently claimed invention, and respectfully request the rejection be withdrawn.

Claim Rejection under 35 U.S.C. § 102(b), Second Rejection

Claims 1-6 and 10-13 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Manafi et al (J. Applied Bacteriology, 1990). Specifically, the Action alleges the cited reference disclosed a composition comprising an L-alanine-7-amido-4-methylcoumarin, which produces a fluorescent color change when cleaved by the L-alanine-aminopeptidase found in the cell wall of Gram-negative bacteria.

Applicant respectfully traverses this rejection and submit the cited reference does not teach each and every element of the claims. Applicant submits the cited reference does not disclose a composition for detecting a target microorganism in a sample, comprising a conditionally detectable marker that undergoes a color change when reacted upon by a viable microorganism in the sample, and a substrate for an aminopeptidase, wherein said aminopeptidase is substantially absent from the target microorganism wherein said target microorganism is selected from the group consisting of *Salmonella*, *Listeria*, *E.coli* OH157, *Campylobacter*, *Staphylococcus aureus*, *Cryptosporidium*, and *Giardia*, wherein said substrate comprises a signal moiety, the signal moiety capable of providing a detectable signal when cleaved by substantially all non-target microorganisms, and wherein said conditionally detectable marker and said substrate for an aminopeptidase are not the same molecule.

Thus, Applicant submits the cited reference does not anticipate the present claims and respectfully request the rejection be withdrawn.

Claim Rejection under 35 U.S.C. § 102(e)

Claims 1-7 and 13 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Tuompo et al (U.S. Patent No. 5,420,017). Specifically, the Action alleges the cited reference teaches detection of Gram-negative bacteria in a sample via a color change.

Applicant respectfully traverses this rejection and submit the cited reference does not teach each and every element of the claims. Specifically, the cited reference does not teach a composition for detecting a target microorganism in a sample, comprising a conditionally detectable marker that undergoes a color change when reacted upon by a viable microorganism in the sample, and a substrate for an aminopeptidase, wherein said aminopeptidase is substantially absent from the target microorganism wherein said target microorganism is selected from the group consisting of *Salmonella*, *Listeria*, *E.coli* OH157, *Campylobacter*, *Staphylococcus aureus*, *Cryptosporidium*, and *Giardia*, wherein said substrate comprises a signal moiety, the signal moiety capable of providing a detectable signal when cleaved by substantially all non-target microorganisms, and wherein said conditionally detectable marker and said substrate for an aminopeptidase are not the same molecule.

Applicant submits the cited reference teaches methods for detecting Gram negative bacteria (target microorganism) whereby reduction of the chromogenic reagent yields a colored product and indicates the presence of the target microorganism. (See claim 1, U.S. Patent No. 5,420,017). Applicant submits the present claims are in direct contrast to the teachings of this reference in that a color change indicates the *absence* of the target microorganism. Thus, Applicant submits the cited reference does not anticipate the present claims, and respectfully request the rejection be withdrawn.

Claim Rejection under 35 U.S.C. § 103(a), First Rejection

Claims 1-6 and 10-13 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious in view of Carr et al (U.S. Patent No. 5,064,756). Specifically, the Action alleges the cited reference teaches a kit for antibiotic sensitivity testing whereby a color change associated with a particular aminopeptidase substrate indicates the susceptibility of the microorganism. The Action further alleges it would have been obvious to use any aminopeptidase substrate for testing the presence of a microorganism.

Applicant respectfully traverses this rejection and submit nothing in the cited reference suggests the presently claimed invention. Applicant submits that in fact, the cited reference teaches away from the present claims. Applicant submits the present claims relate to the surprising result that, contrary to the general prevailing theory disclosed by the cited art, not all microorganisms express the enzyme L-alanine aminopeptidase. Thus, the present invention comprises a presumptive detection of a target microorganism can be achieved colorimetrically in a suitable medium containing a conditionally detectable marker and their identity confirmed by the absence of an enzymatic activity known to be present in substantially all non-target microorganisms. (See lines 1-11, page 18 of the instant specification). Thus, Applicant submits that nothing in the cited reference teaches or suggests the present claims. Accordingly, Applicant submits this rejection has been obviated and respectfully requests the rejection be withdrawn.

Claim Rejection under 35 U.S.C. § 103(a), Second Rejection

Claims 1-6 and 10-13 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious in view of Manafi et al. (J. Applied Bacteriology, 1990). Specifically, the Action alleges the cited reference teaches a composition comprising a marker L-alanine-7-amido-4-methylcoumarin, which produces a fluorescent color change when cleaved by the L-alanine-aminopeptidase found in the cell wall of Gram-negative bacteria, and that it would have been obvious for one of skill in the art to incorporate any L-alanine-7-amido-4-methylcoumarin derivative to detect bacteria.

Applicant traverses this rejection and submit the cited reference teaches away from the present claims. Specifically, the cited reference teaches detecting the *presence* of the target microorganism (Gram-negative bacteria) by change in the detectable marker, while the present claims recite the colorimetric marker indicates the *absence* of the target microorganism. (See lines 1-11, page 18 of the instant specification). Applicant submits nothing in the cited reference teaches or suggests the present claims. Thus, Applicant submits one of skill in the art would not have found the present claims obvious in light of the cited reference.

Accordingly, Applicant submits this rejection has been obviated and respectfully requests the rejection be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

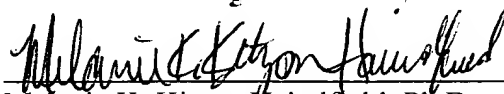
Application No. 09/940,682

Reply to Office Action dated August 9, 2006

All of the claims remaining in the application are now believed to be allowable.
Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

A handwritten signature in black ink, appearing to read "Melanie K. Kitzan Haindfield", written over a horizontal line.

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